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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,741	05/01/2001	Samuel T. Henderson	ACC.01	3451
25871	7590	11/23/2001		EXAMINER
SWANSON & BRATSCHUN L.L.C. 1745 SHEA CENTER DRIVE SUITE 330 HIGHLANDS RANCH, CO 80129				BAHAR, MOJDEH
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/845,741	HENDERSON, SAMUEL T.
	Examiner Mojdeh Bahar	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
  - 4a) Of the above claim(s) 5,6,8-10 and 12-19 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,7 and 11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4 &amp; 5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 7 and 11, drawn to a method of treating or preventing dementia comprising administering an effective amount of MCT or a prodrug thereof, classified in class 514, subclass 558+.
- II. Claims 5-6, 8-9 and 13 (in part), drawn to a method of treating or preventing dementia comprising administering an effective amount of MCT and L-carnitine, classified in class 514, subclass 558+.
- III. Claim 10, drawn to a method of treating or preventing dementia comprising administering an effective amount of free medium chain fatty acid, classified in class 514, subclass 558+.
- IV. Claim 12, drawn to a method of treating or preventing dementia comprising administering an effective amount of a therapeutic agent which induces utilization of fatty acid and development of ketones, classified in class 514, subclass 1+ (depending on the therapeutic agent).
- V. Claims 13(in part) and 14-15, drawn to a method of treating or preventing dementia comprising administering an effective amount of L-carnitine and a therapeutic agent, classified in class 514, subclasses 1+ (depending on the therapeutic agent).

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VI. Claims 16-18, drawn to a composition comprising a MCT or a prodrug thereof, classified in class 514, subclass 558+.

VII. Claim 17, drawn to a composition comprising free medium chain fatty acid classified in class 514, subclass 558+.

VIII. Claim 19, drawn to a composition comprising a therapeutic agent which induces utilization of fatty acid and development of ketones, classified in class 514, subclass 1+ (depending on the therapeutic agent).

Inventions I and VI, III and VII, I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case alzheimer's disease can be treated acetylcholinesterase.

Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Inventions VI-VIII are unrelated because they have different modes of operation.

During a telephone conversation with Mr. Barry Swanson a provisional election was made without traverse to prosecute the invention of Group I, claims 1-4, 7 and 11. Affirmation of this election must be made by applicant in replying to this Office action. Claims

5-6, 8-10 and 12-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-4, 7 and 11 are herein examined on the merits.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. and Veech (USPN 6,316,038).

Mak et al. teaches that ketogenic diets are known to improve cognitive functioning, see abstract.

Veech (USPN 6,316,038) teaches a method for treating Alzheimer's disease and its symptoms and manifestations, including dementia, employing a ketogenic (medium chain triglycerides) diet, see col. 3, lines 21-59 in particular. Veech (USPN 6,316,038) teaches an example of a ketogenic diet wherein at each of the three meals the patient consumes 48-50 g of fat, see particularly col. 10, lines 56-67. Veech (USPN 6,316,038) further teaches that increase of ketone bodies is effective in the treatment of Alzheimer's disease, see particularly col. 5, lines 11-29. Veech also teaches that both oral and parenteral administration of triglycerides can increase blood ketones, see col. 9 lines 62-65, see also col. 20, lines 16-23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ medium chain triglycerides in a method of treating Alzheimer's disease and dementia associated therewith.

One of ordinary skill in the art would have been motivated to employ medium chain triglycerides in a method of treating Alzheimer's disease and dementia associated therewith because medium chain triglycerides are known to increase the level of ketone bodies in the blood and the increase of ketone bodies in the blood is known to be useful in treating Alzheimer's disease. Therefore one of ordinary skill in the art would be motivated to increase ketone bodies in order to treat Alzheimer's.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
November 19, 2001

*Minna Moezie*  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
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